

**REMARKS**

Applicant thanks the Examiner for the thorough consideration given the present application. Claims 6, 8 and 9 were previously cancelled herein without prejudice to or disclaimer of the subject matter set forth therein. Claims 1-5, 7, and 10-12 are pending. Claims 1, 2, 5 and 7 are amended, and claims 10-15 are added. Claims 1, 2 and 7 are independent. The Examiner is respectfully requested to reconsider the rejections in view of the amendments and remarks set forth herein.

**Examiner Interview**

If, during further examination of the present application, a discussion with Applicant's Representative would advance the prosecution of the present application, the Examiner is encouraged to contact Carl T. Thomsen (Registration No. 50,786) at 1-703-208-4030 (direct line) at his convenience.

**Claim for Priority**

It is gratefully appreciated that the Examiner has acknowledged Applicant's claim for foreign priority based on ZA 03/5160 filed on July 2, 2003.

**Rejection Under 35 U.S.C. § 112, first paragraph**

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 112, first paragraph. This rejection is respectfully traversed.

The Examiner states that the original specification does not disclose *Melaleuca dissitiflora*, and *Melaleuca linariiflora*, as recited in claims 1, 2, and 7.

In order to overcome this rejection, Applicants have amended claims 1, 2, and 7 to delete *Melaleuca dissitiflora*, and *Melaleuca linariiflora*.

The Applicant respectfully submits that the claims, as amended, are fully supported by and adequately described in the written description of the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

**Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 1-5 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

The Examiner has set forth certain instances wherein the claim language is not clearly understood.

In order to overcome this rejection, the Applicant has amended claims 1, 2, and 7 to address the issue pointed out by the Examiner, and to clarify that the film forming liquid consists of “no more than more than the water repellent agent and the antimicrobial agent.”

Applicant respectfully submits that the claims, as amended, particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

**Rejections Under 35 U.S.C. § 103(a)**

Claims 1-5 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over GB Patent Publication 965,236 in view of Van Cleave (U.S. Patent 4,037,937) and Saleh et al. (U.S. Patent 6,387,382).

This rejection is respectfully traversed.

**Amendments to Independent Claims 1, 2 and 7**

While not conceding the appropriateness of the Examiner's rejection, but merely to advance prosecution of the present application, each of independent claims 1, 2 and 7 has been amended to recite a combination of features, including *inter alia*

“consisting of a water repellent agent and an antimicrobial agent to constitute a film forming liquid,”

“the antimicrobial agent consisting of an essential oil of *Melaleuca alternifolia*, wherein the film forming liquid consists of no more than the water repellent agent and the antimicrobial agent.”

The Applicant respectfully submits that the combination of features set forth in each of independent claims 1, 2 and 7 is not disclosed or made obvious by the prior art of record, including GB 965,236, Van Cleave, and Saleh et al.

**Regarding GB 938,236**

The Examiner points out GB 965,236 page 2, lines 33-36 states that the composition “may” contain components in addition to polysiloxane and an anti-bacterial.

However, the Examiner's interpretation of the indefinite word “may” to overlook that fact that entire GB 965,236 document refers to a composition in which the polysiloxane and anti-microbial are but a small proportion of the overall composition (See, for example, the tables on pages 2 and 3). The claims and other clauses of the specification, when considered in their entirety, calls for a composition containing at least a polysiloxane, an anti-microbial

agent and a major proportion of an easily vaporizable ingredient which has no irritant effect on the skin, such as water or low molecular weight alcohol.

As the Examiner knows well, **MPEP 2141.02** states that

“Ascertaining the differences between the prior art and the claims at issue requires interpreting the claim language, and considering both the invention and the prior art references as a whole.”

In particular, **MPEP 2141.02 VI.**, is entitled “PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS”, and states the following;

“A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).”

First of all, the Applicant respectfully submits that the Examiner has failed to consider GB 965,236 in its entirety.

Secondly, the Applicant submits that the Examiner’s reliance on page 2, lines 33-36 of GB 965,236, which states “may contain ... a major proportion of easily vaporizable ingredients” to support his allegation “the ‘236 patent clearly states that the polysiloxanes

and the anti-bacterial agent are required and that all other components are optional,” is not proper and should be withdrawn.

The Examiner’s position is refuted by the fact that every one of the embodiments (Examples I, II, and III), and every one of the claims (claims 1-7) set forth in GB 965, 236 explicitly discloses a composition having more than two components.

The Applicant’s position is supported by the fact that every one of the embodiments (Examples I, II, and III), and every one of the claims (claims 1-7) set forth in GB 965, 236 explicitly discloses a composition having more than two components.

In addition, the word “may” on line 34 makes the sentence in which is contained “indefinite.” Certainly, in view of fact that every one of the embodiments (Examples I, II, and III), and every one of the claims (claims 1-7) set forth in GB 965, 236 explicitly discloses a composition having more than two components, it is not reasonable for the Examiner to conclude that the indefinite word “may” would lead one skilled in the art to conclude that GB 965,236 discloses any composition in which “the polysiloxanes and the anti-bacterial agent are required and that all other components are optional.”

Therefore, the Applicant submits that it not proper for the Examiner to cite GB 965,236 as the “base reference” that can be used in combination with Van Cleave and Saleh et al. to reject the claims of the present invention

**Regarding Van Cleave**

Van Cleave merely provides a treatment directed at preventing the phenomenon of capillary action and surface tension which arises within the ear canal. The primary purpose

of the Van Cleave treatment is to reduce surface tension in the water retained in the ear canal, thereby to allow the water to run out normally when the person's head is tilted (column 4; lines 10 to 17). This is why Van Cleave proposes the use of an aqueous surface tension reducing agent into the ear (column 2; lines 6 to 11).

In its entirety, the Van Cleave patent teaches the use of surface tension reducing agents, surface active agents or surfactants, the primary purpose of which is to reduce the capillary adhesion of water retained in the outer ear canal to the skin of the canal. The document goes on to list a large number of such surface active agents.

Against this, the present patent application proposes the use of an inert oil (in the form of silicone oil in the preferred form of the invention) simply to line the ear canal with a thin film of oil prior to swimming, the intention being simply to prevent water contact during and after swimming, even if the water is retained within the ear after swimming.

This is a greatly simplified approach, the advantage of which lies in a lower constituent cost and a greatly reduced manufacturing cost.

In support of the use of Van Cleave as a secondary reference, the Examiner relies on wording drawn from several different places within the document, rather than from a clear, coherent description of the invention found in one place in the document, almost creating a mosaic of references.

As the Examiner knows well, rejections under 35 U.S.C. § 102(b) and/or 103(a) require a clear statement, describing the invention. It is submitted that the Van Cleave

reference does not contain such a clear statement or description of the invention in its entirety.

Further, Van Cleave provides no suggestion that “the liquid, non-ionic, substantially water insoluble, aqueous surface tension reducing agent” of Van Cleave, teaches or suggests

“wherein the film forming liquid consists of no more than the water repellent agent and the antimicrobial agent,” as set forth in independent claims 1, 2, and 7

Therefore, Van Cleave cannot improve upon base reference GB 965,236 to arrive at the invention set forth in each of independent claim 1, 2, and 7.

**Regarding Saleh et al.**

Saleh et al. relates to an oil-in-water emulsion (column 1; lines 5 to 10). The multipurpose skin preparation of Saleh is an example of silicone-based skin preparations, of which there are many. Throughout the document, reference is made to the fact that the skin preparation is an emulsion that contains a large number of constituents in both its oil and aqueous phases.

The Saleh et al. composition is very different from the very simple film forming oil-in-oil formulation described and claimed in the present patent application.

The Examiner relies on the assumption that a liquid formulation is “inherently capable of being instilled in the outer ear canal in droplet form.” It is clear from the Saleh et al. document, however, that the entire description and the claims are directed to relatively thick emulsions that are to be applied to the skin in cream form and this assumption is therefore untenable.

Silicone polymers are well known as film forming liquids, as pointed out in the Saleh et al. document (column 1; lines 63 to 67), but the Saleh et al. document makes use of a large number of these polymers to create the oil phase of an emulsion. Once again this is very different from the simple oil-in-oil formulation of the ear drops of the invention.

While Sahel et al. column 7, lines 59-60 discloses that an antimicrobial agent (tea tree oil) may be present in a range of from about 0.001% to about 4%, there is no teaching or suggestion that the only other component of the composition is the presently claimed "water repellant agent."

Therefore, the Applicant submits that the combination GB 965, 236, Van Cleave, and Saleh et al. does not disclose or suggest the present invention in a manner sufficient to anticipate or make obvious the combination of features set forth in any of **independent claims 1, 2 and 7**.

### **Summary**

At least for the reasons explained above, the Applicants respectfully submit that the combination of features set forth in each of independent claims 1, 2 and 7 is not disclosed or made obvious by the prior art of record, including GB 965,236, Van Cleave, and Saleh et al.

Therefore, independent claims 1, 2 and 7 are in condition for allowance.

### **Dependent Claims**

The Examiner will note that **dependent claims 10-15** have been added to set forth additional novel features of the invention.



In particular, each of **dependent claims 10-12** recites *inter alia*

“wherein the film forming liquid includes 75 to 98% by volume of polysiloxane as the water repellant agent, and 2 to 25% by volume of *Melaleuca alternifolia*. ”

As pointed out above, while Sahel et al. column 7, lines 59-60 discloses that an antimicrobial agent (tea tree oil) may be present in a range of from about 0.001% to about 4%, there is no teaching or suggestion that the only other component of the composition is the presently claimed “water repellant agent.”

Therefore, **dependent claims 10-12** should be allowable.

Further, **each of dependent claims 13-15** recites *inter alia*

“wherein the film forming liquid includes 98% by volume of polysiloxane as the water repellant agent, and 25% by volume of *Melaleuca alternifolia*. ”

As pointed out above, Sahel et al. column 7, lines 59-60 merely discloses that an antimicrobial agent (tea tree oil) may be present in a range of from about 0.001% to about 4%. In addition, there is no teaching or suggestion that the only other component of the composition is the presently claimed “water repellant agent.”

Therefore, **dependent claims 13-15** should be allowable.

All dependent claims are in condition for allowance due to their dependency from allowable independent claims, or due to the additional novel features set forth therein.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

**CONCLUSION**

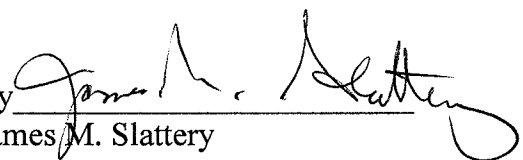
All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. It is believed that a full and complete response has been made to the outstanding Office Action, and that the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, he is invited to telephone Carl T. Thomsen (Reg. No. 50,786) at (703) 208-4030 (direct line).

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly extension of time fees.

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Respectfully submitted,

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